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Lisinopril as a liquid dosage form intended for pediatric use

Abstract: Purpose The U.S. National Institute of Health (NIH) funded the Pediatric Trials Network to design, in part, pediatric liquid dosage forms of drugs for commercial production. The goal of this project is to develop a diluent for lisinopril and study the stability and palatability properties of the formulation. This study will investigate the stability of the drug as a function of pH, temperature, and presence of amino acids as stabilizing agents; as well as the presences of different flavorings. Methods Lisinopril solutions (10mg/10ml) were prepared under the following conditions: four solutions were prepared in a pH 4.66 buffer solution and stored at different temperatures (4, 25, 35, 45&[deg]C). Three separate solutions were prepared with buffer adjusted to pH 4.16, 5.15, 5.7 and stored at room temperature (25&[deg]C). The remaining three solutions were prepared with a 3:2 mol ratio of amino acid (glycine, alanine and 50/50 glycine/alanine to lisinopril. The lisinopril solutions were assayed over time using HPLC (UV Detection and 20% (v/v) acetonitrile/buffer mobile phase). In addition, five flavors were tested with Ora-Sweet/Ora-Plus solutions in order to determine a palatable diluent to mask the taste of the lisinopril solution. The diluents were first tested alone to optimize the product for sweetness, flavor, and consistency. The selected diluent mixtures were then tested with lisinopril. The diluent with lisinopril was then assayed using the same HPLC system as stated above. Results The goal is to prepare a palatable and stable lisinopril mixture with a shelf life of 18-24 months that can be scaled for commercial production. Stability testing as a function of buffer and temperature are ongoing. Once the most stable buffer (pH) solution is identified, stability testing will include lisinopril with the selected flavoring/diluent. To date, a diluent ratio of 1 drop flavoring:10mL Ora-Sweet: 10mL Ora-Plus) mixed in equal parts with a 2mg/ml solution of lisinopril yields a palatable dosage form. Conclusion The final preparation will be one that offers the greatest stability and palatability for inclusion in clinical trials outlined by the Pediatric Trials Network (PTN).

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